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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,090	03/01/2001	Yoav Eichen	18363.0002/P002	1528

24998 7590 12/07/2004

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP  
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Washington, DC 20037

EXAMINER
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KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,090

Applicant(s)

EICHEN ET AL.

Examiner

Young J. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 15, 16 and 18-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 12, 13, 15, 16, 18-31 and 34-45 is/are rejected.
- 7) ☒ Claim(s) 2-9, 11, 32, 33 and 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/26/00 & 1/2/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/14/03; 6/3/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

#### ***Preliminary Remark***

All objections/rejections hereto not reiterated should be considered withdrawn.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Drawings***

The drawings received on October 26, 2000 and the replacement Figure 30 received on January 2, 2002 are acceptable.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1, 10, 12, 13, 15, 16, 18-23, 31, 34, 35, 37, 38, 41, 43, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Bamdad (U.S. Patent No. 6,306,584 B1, issued October 23, 2001, filed April 10, 1997).

Bamdad discloses an assay system/kit comprising: a) at least two electrodes, having oligonucleotides attached thereto; b) an electronic module arranged and configured to measure electric conductance between the at least two electrodes, wherein they nucleic acid hybridization occurs, a conductive bridge between the two electrodes are formed (column 19, lines 20-29; Figures 11 and 12; column 5, line 12). A target nucleic acid is known in the art as evidenced by Bamdad, are being polymers which conduct electrical current (column 19, lines 27 and 28), thus considered to be a reagent which forms a conductive bridge between the at least two electrodes of a set.

Bamdad discloses an array device comprising a plurality of electrodes comprising a plurality of nucleic acids (column 19, beginning at line 58 through column 20, line 4).

Bamdad discloses that the detection could be achieved not only for nucleic acids, but also for proteins (column 6, lines 8-10).

Therefore, Bamdad anticipates the invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584 B1, issued October 23, 2001, filed April 10, 1997) in view of Becker et al. (U.S. Patent No. 5,993,632, issued November 30, 1999, filed February 1, 1999, priority, February 23, 1996).

The teachings of Bamdad have been discussed above.

Bamdad does not explicitly teach that the distance between the two electrodes are less than 100 micrometer (or  $\mu\text{m}$ ).

Becker et al. disclose an apparatus which comprises a plurality of electrodes which are spaced 20 microns apart, evidencing that spacing of the electrodes in an apparatus are well within the purview of an ordinarily skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Bamdad with the well known knowledge, as evidenced by Becker et al., to arrive at the claimed invention for the following reasons.

While Bamdad is not explicit in how far apart the "at least two electrodes" must be, one of ordinary skill in the art would have been able to derive an optimal distance via routine experimentation provided that the technology involved in producing an apparatus comprising electrodes which are spaced microns apart, as evidenced by Becker et al., would have been well known and well established in the art.

MPEP 2144.05 (II), in discussing optimization through routine experimentation, states that:

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are

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disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)"

While the instantly claimed range is not temperature but for distance between the two electrodes, it is clear that the range recited by the instant claim is not critical as the claim recites that the range is any distance less than 100  $\mu\text{m}$ .

Further, MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success. Given that the technology had been advanced to produce an apparatus comprising electrodes having the space of less than 100  $\mu\text{m}$  therebetween, one of ordinary skill in the art at the time the invention was made would have had a clear expectation of success at producing an assay device comprising electrodes with the claimed spacing.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 24-30, 39-42, and 45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/452,139. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 24-30, 39-42, and 45 of the instant application is drawn to a method of assaying for a target molecule in a sample, wherein the method involves an assay device having at least two electrodes comprising a recognition moiety immobilized thereto, followed by contacting the assay device with a target to form a complex, forming a bridge between the two electrodes, whereby the measurement of the conductance between the two electrodes indicates the presence of a target in the sample.

Claims 1-15 of the '139 application is drawn to a method for detecting a target nucleic acid molecule in a sample, wherein the method involves the use of two electrical conductors (or electrodes) comprising oligonucleotide probes (or recognition moiety) immobilized thereto, followed by the contacting of the oligonucleotide probes with the target nucleic acid, forming a conductive coating (or bridge), whereby an electrical current between the oligonucleotide probes indicate the presence of the target nucleic acid molecules in a sample.

While not verbatim, the claims are obvious over each other in their steps as both of the methods require at least two electrodes comprising probes thereto, wherein the binding of the target moiety between the two probes generate an electrical current, whereby the electrical current determines whether the target molecule is present or not in a sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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### ***Conclusion***

Claims 1, 10, 12, 13, 15, 16, 18-23, 31, 34-38, 41, 43, and 44 are rejected.

Claims 2-9, 11, 32, 33, and 46 are objected to for being dependent on a rejected claim(s).

Claims 24, 25, 26-30, 39, 40, 42, and 45 are free of prior art.

Claims 24-30, 39-42, and 45 are provisionally rejected under double patenting rejection.

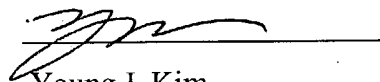
### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a



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general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim

Patent Examiner

Art Unit 1637, YOUNG J. KIM

11/29/04 PATENT EXAMINER

yjk